

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 02N-0315]

#### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices: Humanitarian Use Devices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by *[insert date 30 days after date of publication in the **Federal Register**]*.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Medical Devices: Humanitarian Use Devices—21 CFR Part 814–Subpart H  
(OMB Control Number 0910–0332)—Extension**

This collection implements the humanitarian use device (HUD) provision under section 520(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(m)) and 21 CFR part 814, subpart H. Under section 520(m) of the act, FDA is authorized to exempt an HUD from the effectiveness requirements of sections 514 and 515 of the act (21 U.S.C. 360d and 360e) provided that the device: (1) Is used to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States; (2) would not be available to a person with such a disease or condition unless the exemption is granted, and there is no comparable device, other than another HUD approved under this exemption, available to treat or diagnose the disease or condition; and (3) the device will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The information collection will allow FDA to determine whether to: (1) Grant HUD designation of a medical device, (2) exempt a HUD from the effectiveness requirements in sections 514 and 515 of the act provided that the device meets requirements set forth in section 520(m) of the act, and (3) grants marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making those determinations. Also, this information enables FDA to determine whether the holder of a humanitarian device exemption (HDE) is in compliance with the HDE requirements.

*Description of respondents:* Businesses or others for-profit.

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per response	Total Hours
814.102	20	1	20	40	800
814.104	15	1	15	320	4,800
814.106	15	4	60	50	3,000
814.108	12	1	12	80	960
814.116(e)(3)	1	1	1	1	1
814.124(a)	5	1	5	1	5
814.124(b)	1	1	1	2	2
814.126(b)(1)	15	1	15	120	1,800
Total					11,368

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
814.126(b)(2)	15	1	15	2	30

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Generally, the information requested from the respondents represents an accounting of information already in the possession of the applicant.

In the **Federal Register** of June 26, 1996 (61 FR 33232), FDA published the final rule for HUDs and based its estimates on comments received to the proposed rule (57 FR 60491, December 21, 1992); industry contact; and internal FDA benchmark factors (such as the number of premarket approval applications processed). The numbers generated in the current estimate as shown in tables 1 and 2 of this document are based upon those prior

estimates. This is still a relatively new program, and the data acquired from the past several years has remained fairly stable and consistent.

Dated: October 11, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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